Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13031

7 - PROCEDURES

[redacted]

Clinical Laboratory R[illegible]rt

[redacted]

Patient Name [redacted] Date Drawn 05/29/98 Date Received 05/29/98 [redacted] Date of Report 05/29/98

Sex F Age 28 [redacted] ID Number Account Number [redacted]

Ordering Physician [redacted] CLIA # [redacted] Specimen Number [redacted] Time Drawn 0120

Patient ID Soc Sec Number [redacted]

CLIENT INFO:

********** SPECIAL REPORT **********

ER TOX SCREEN, BLOOD

SPECIMEN POSITIVE FOR: DIAZEPAM = 82.0 MCG/L

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NEGATIVE FOR ALL OTHER DRUGS. SPECIMEN TESTED FOR:

ACETAMINOPHEN	IMIPRAMINE
ACETONE	ISOPROPANOL
AMITRIPTYLINE	MEPROBAMATE
AMOBARBITAL	METHANOL
CHLORDIAZEPOXIDE	METHYPRYLON
DESALKYLFLURAZEPAM	N-DESMETHYLDOXEPIN
DESIPRAMINE	NORDIAZEPAM
DIAZEPAM	NORTRIPTYLINE
DOXEPIN	PENTOBARBITAL
ETHANOL	PHENOBARBITAL
ETHCHLORVYNOL	SALICYLATES
GLUTETHIMIDE	SECOBARBITAL

[redacted]

[redacted]

000002

[redacted]

[redacted]

[redacted]

ACCOUNT NUMBER	S.L.I. ACCESSION NUMBER
[redacted]	[redacted]

PATIENT NAME: [redacted]

REFERRING PHYSICIAN: [redacted]

[redacted]

PATIENT I.D. NUMBER	DRAWN
[redacted]	05/29/98 2:15

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TEST NAME	RESULTS	REFERENCE RANGES
APPL CSF	Nonreactive	Nonreactive

BORRELIA burgdorferi (LYME DISEASE) IgG & IgM ANTIBODY INDICES

Intra-blood-brain barrier synthesis of B. burgdorferi

B. burgdorferi IgG Ab INDEX	**	Less than 1.0

** Antibody Index not calculated because elevated specific antibody was not found in BOTH the CSF and serum.

B. burgdorferi IgM Ab INDEX	**	Less than 1.0

** Antibody Index not calculated because elevated specific antibody was not found in BOTH the CSF and serum.

IgG (loc)	Less than 0.1	Less than 0.1 mg/dL
IgG INDEX	0.54	Less than 0.7
CNS IgG SYNTHESIS RATE	Less than 3.3	Less than 3.3 mg/24hr
IgM (loc)	Less than 0.01	Less than 0.01 mg/dL
[redacted] INDEX	0.05	Less than 0.10
[redacted]MIN INDEX	5.6	Less than 9.0
IgG CSF	3.4	0.5-6.1 mg/dL
IgG SERUM	1120	600-1600 mg/dL
IgM SERUM	107	40-250 mg/dL
ALBUMIN CSF	26.5 *	13-24 mg/dL
ALBUMIN SERUM	4740	3700-5000 mg/dL
IgM CSF	0.03	0.02-0.20 mg/dL
B. burgdorferi IgG Abs CSF	Less than 15	Less than 15 Units
B. burgdorferi IgM Abs CSF	Less than 15	Less than 15 Units
B. burgdorferi IgG Abs Serum	Less than 15	Less than 15 Units
B. burgdorferi IgM Abs Serum	Less than 15	Less than 15 Units

BORRELIA burgdorferi IgG & IgM ANTIBODY INDICES, EIA/NEPH:
A Borrelia burgdorferi IgG and/or IgM Antibody Index >2.0 is strong evidence of intrathecal synthesis of B. burgdorferi-

000003

[redacted]

Continued on page: 2

[redacted] .D.,Ph.D.

[redacted]

[redacted]

COUNT NUMBER	S.L.I. ACCESSION NUMBER
[redacted]	[redacted]

PATIENT NAME [redacted]

REFERRING PHYSICIAN [redacted]

NOTES

PATIENT I.D. NUMBER	DRAWN
[redacted]	

RECEIVED	REPORTED
05/30/98 17:26	06/01/98 00:36

specific antibodies and suggests Lyme neuroborreliosis if neurosyphilis has been ruled out. Negative results, however, do not rule out neuroborreliosis, especially during very early infections or in immunosuppressed individuals. A disease duration of 4-5 weeks is probably required before IBBB synthesis if specific IgG is demonstrable. An elevated Albumin Index is suggestive of blood-brain barrier damage. RECOMMENDATIONS: B. burgdorferi IgG or IgM Antibody Index results between 1.0 and 2.0 are considered indeterminate. [redacted] recommends further evaluation of indeterminate B. burgdorferi Antibody Indices with additional paired CSF and serum specimens and with B. burgdorferi DNA by PCR (test code #[redacted] on CSF, especially for diagnosis of early disease, if clinically indicated. Please provide the [redacted] accession numbers of the current specimens when submitting follow-up specimens. The specimens will be tested simultaneously to optimize the utility of the results. All specimens are stored frozen for six weeks for additional testing. (308)

VDRL, CSF: Although false positives in the VDRL test are generally restricted to serum and are not usually found in VDRL CSF, the possibility of false positives must always be considered. The VDRL CSF test has a sensitivity (positivity in disease) for neurosyphilis of only 50% and a specificity (negativity in health) of about 99%. The FTA-ABS CSF test has a sensitivity for neurosyphilis and a specificity of 100% and 99.2% respectively. Hence FTA-ABS CSF should be considered in all cases if clinically indicated. Monitoring the CSF VDRL is useful because with successful treatment the VDRL titer is expected to decrease about fourfold at three months and eightfold at six months (J. Am Assoc., 1985; 253;1296-12[redacted] provides simultaneous testing of CSF [redacted] treatment and at 3 and 6 months after trea[redacted] Please call us if you want FTA-ABS and FTA-ABS IgM testing on CSF

000004

[redacted] [redacted] [redacted]

ed on page: 3

[redacted]

[redacted]

ACCOUNT NUMBER	S.L.I. ACCESSION NUMBER
[redacted]	[redacted]

PATIENT NAME: [redacted]

REFERRING PHYSICIAN: [redacted]

[redacted]

PATIENT I.D. NUMBER	DRAWN
[redacted]	

RECEIVED	REPORTED
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we have frozen. Please provide us the [redacted] accession number of the first specimen when you send follow-up specimens so we can test them simultaneously as is necessary to optimize the usefulness of the results. All samples are stored frozen for four weeks at [redacted]

Based on a recent FDA Public Health Advisory communique (July 7, 1997), assays for anti-Borrelia burgdorferi (anti-Bb) should be used by clinicians only to support a clinical diagnosis of Lyme Disease. The results should be interpreted only in the context of a two-step testing algorithm, total or class-specific antibodies (IgM or IgG) by EIA or IFA and Western-blot (Immunoblot) assays.

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[redacted]

[redacted]

FINAL REPORT

[redacted]

Pat ent Loc: [redacted]
Dept No:
DOB:
MRN:

DIAGNOSTIC IMAGING REPORT

me: [redacted]

EXAM: 28-May-98 11:20 PM CT HEAD WITHOUT CONTRAST [redacted]

Requested by: [redacted]

History:
ER8 RO BLEED

A noncontrast CT scan of the head is submitted in this 28 year old female a status post arrest while playing soft ball. The present exam is done status post intubation. The present examination shows no subdural hematoma and no intraparenchymal hematoma. There is no hydrocephalus or shift. There is no CT evidence of subarachnoid blood. There is no air fluid level within the sphenoid sinus.

IMPRESSION:

Noncontrast CT scan of the head submitted in a 28 year old female showing:

1. No subdural hematoma and no intraparenchymal hemorrhage.
2. No hydrocephalus or shift.
3. No CT evidence of subarachnoid blood.
4. No air fluid level within the sphenoid sinus.

[redacted]

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Radiologist: [redacted] /signs on line/

Transcribed on: 30-May-98 12:41 PM by [redacted]
Finalized on: 2-Jun-98 10:23 AM by [redacted] M.D.

Attending MD: NO PRIVATE, PHYSICIAN

F I N A L C O P Y

[redacted]

Patient Loc:
Dept No: [redacted]
DOB:
MRN: [redacted]

DIAGNOSTIC IMAGING REPORT

Name: [redacted]

EXAM: 29-May-98 4:40 PM EEG [redacted]

Requested by: [redacted]

[redacted]

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Radiologist: [redacted] /signs on line/

Transcribed on: 1-Jun-98 2:42 PM by [redacted]
Finalized on: 2-Jun-98 5:32 PM by

Attending MD: [redacted]

F I N A L C O P Y

000007

[redacted]

Patient Loc:
Dept No: [redacted]
DOB: [redacted] Sex: F
MRN: [redacted]

DIAGNOSTIC IMAGING REPORT

ame: [redacted]

EXAM: 29-May-98 4:40 PM EEG [redacted]

Requested by: [redacted]

History:
V-FIB ARREST,RESP.FAILURE PEEG# [redacted]

DEPARTMENT OF NEUROPHYSIOLOGY

CONDITIONS OF THE RECORDING: Portable tracing, taken in the ICU. The patient was extubated one hour prior to testing. The patient was awake, alert and cooperative. Speech was difficult because of the intubation.

Background activity of this EEG consists of 10-12 c.p.s. of alpha, 30-50 microvolts seen bilaterally, bisymmetrically in the posterior head regions.

Beta activity is seen at low voltage 15-30 c.p.s. in the anterior and central head regions.

There are no paroxysmal or asymmetrical features to the recording.

A portion of the recording represents normal drowsy state.

Hyperventilation was not performed.

Photic stimulation was performed and produced no change in the record.

Please note, EKG tracing reveals intermittent bigeminy.

IMPRESSION:

Normal EEG. No evidence of underlying focal slowing or seizure activity.

[redacted]

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[redacted]

Patient Loc: [redacted]
Dept No: [redacted]
DOB: [redacted]
MRN: [redacted]

DIAGNOSTIC IMAGING REPORT

Name: [redacted]

EXAM: 30-May-98 9:40 PM CHEST 1 VIEW [redacted]

Requested by: [redacted]

History:
TEMP

Chest exam demonstrates the patient has been extubated. Perihilar infiltrates are markedly improved since 5/29 compatible with improving pulmonary edema.

IMPRESSION:

Small perihilar infiltrates markedly improved since 5/29.

[redacted]

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Radiologist: [redacted] /signs on line/

Transcribed on: 1-Jun-98 9:32 AM by [redacted]
Finalized on: 2-Jun-98 8:24 AM by

Attending MD: [redacted]

F I N A L C O P Y

000009

[redacted] *** ORIGINAL ****PRINTED: 6/05/98 9:37
BY: [redacted]

PATIENT: [redacted]
MR#/ACT#: [redacted]
ADM/DSH DATE: 05/28/98 06/02/98
ORDER #: [redacted]
DOCTOR: [redacted]
COMPLETION DATE: 05/29/98

REFERRING PHYSICIAN: [redacted]
ECHOCARDIOGRAM EXAMINATION

Aortic Root 30 mm (<39)
Left Atrium 25 mm (<41)
Mitral Valve Excursion mm (>19)
EF Slope
Left Ventricle: EF 55-60%
EDD 47 mm (37-56)
ESD 31 mm
IVS 10 mm (6-11)
PW 10 mm (6-11)
Right Ventricle mm (<30)
Pericardial Effusion: NONE

COLOR FLOW & SPECTRAL DOPPLER
Aortic valve: Systolic Flow 1.5 M/S (1.0-1.7)
Peak Systolic Gradient mmHg
Valve Area sq cm
Regurgitation: NONE
Mitral Valve: Area sq cm
Regurgitation: NONE
Tricuspid Valve Regurgitation: NONE
Estimated PA Systolic Pressure
Pulmonic Valve Regurgitation: NONE

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2D and M-mode echocardiographic study with color flow and spectral doppler examination is performed in the standard echocardiographic views. The image quality is fair. The left ventricular cavity size and wall thickness is normal. The left ventricular systolic function is normal and the ejection fraction is estimated to be in the 55-60% range. No gross regional wall motion abnormality is noted. The right ventricular systolic function appears normal. The left atrial size is normal. The right atrial size is normal. The aortic root size is normal.

The aortic valve is poorly visualized but appears to be grossly normal. There appears to be adequate leaflet separation and suggests no aortic stenosis. The mitral valve appears morphologically normal with normal excursion of its leaflets. There is no mitral stenosis. The tricuspid valve appears morphologically normal with normal excursion of its leaflets.

There is no pericardial effusion.

Color flow doppler examination reveals no aortic regurgitation, no mitral regurgitation, and no tricuspid regurgitation.

Spectral doppler examination reveals a peak systolic flow velocity across the aortic valve of 1.5 m/sec which is within normal limits.

** CONTINUED ON NEXT PAGE **

[redacted] *** ORIGINAL ****PRINTED: 6/05/98 9:37
BY: [redacted]

PATIENT: [redacted]
MR#/ACT#: [redacted]
ADM/DSH DATE: 05/28/98 06/02/98
ORDER #: [redacted]
DOCTOR: [redacted]
COMPLETION DATE: 05/29/98

CONCLUSIONS:
1. Normal 2D echocardiographic study.

[redacted]
MD

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[redacted] 06/01/1998 12:41:38 [redacted]
28 years Female

BP: [redacted]

Room: [redacted]
Oper: [redacted]

Rx:
Dx:

Rate	65
PR	142
QRSD	79
QT	372
QTc	387

--AXIS--

P	-1
QRS	27
T	5

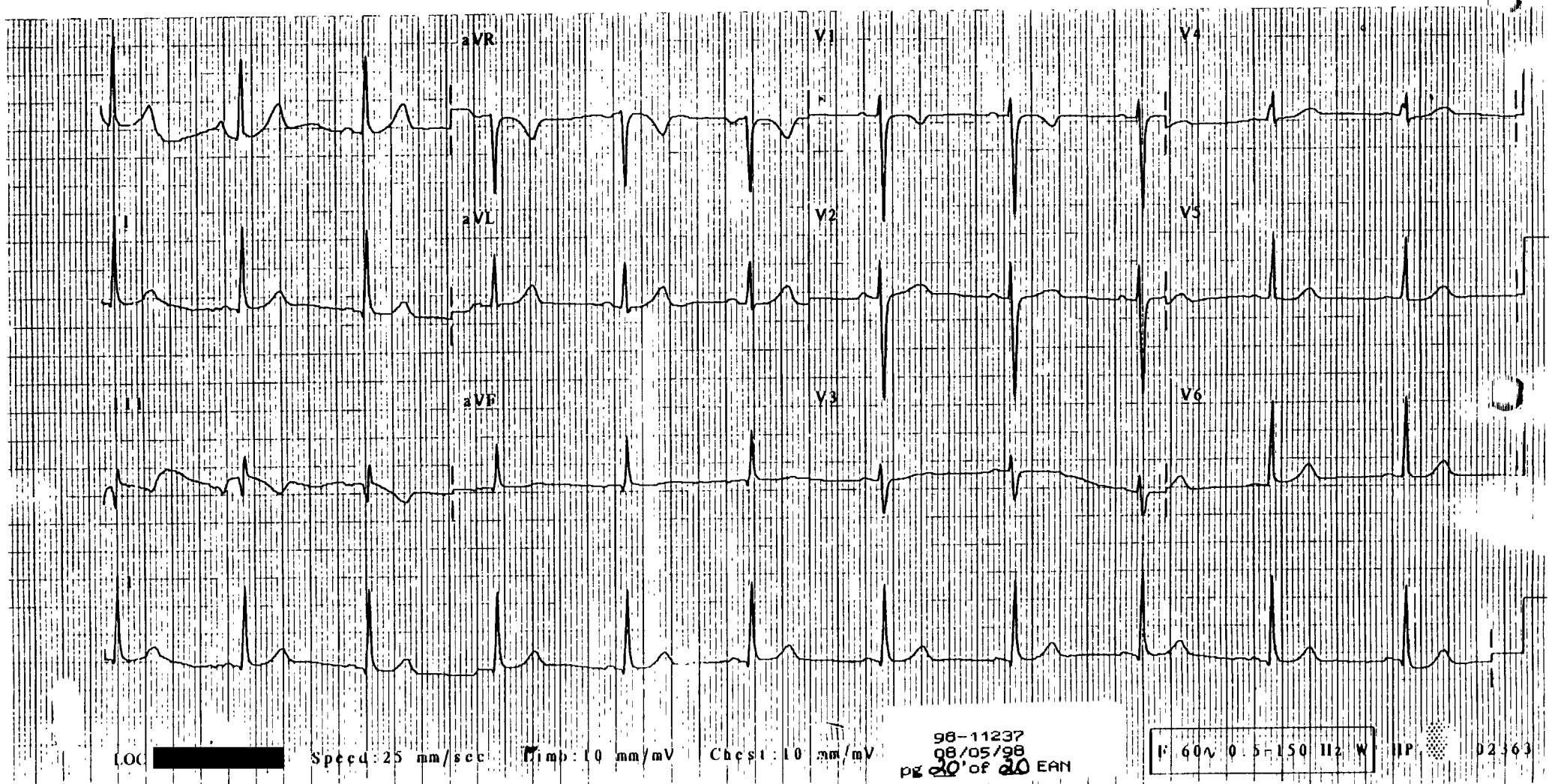
. Normal sinus rhythm, rate 65.....Normal P axis, PR, rate & rhythm

[redacted] ested by:

- NORMAL ECG -

PRELIMINARY-MD MUST REVIEW

0000012



LOC [redacted] Speed:25 mm/sec Limb:10 mm/mV Chest:10 mm/mV

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F 60∿ 0.5-150 Hz W HP 02363

[redacted]

RIGHT AND LEFT HEART CATHETERIZATION

Last Name: [redacted] **First Name:** [redacted]

Procedure Date: 6/2/98 **Medical Record #:** [redacted] **Billing #:** [redacted]

Date of Birth: [redacted] **Gender:** F **Cath #:** [redacted]

Performing Physician: [redacted] M.D.

Referring Physician: [redacted]

History

The patient is a 28-year-old female admitted with unstable angina.

Risks

Risk factors: No cardiac risk factors.

Indications/Procedure Performed

Indication for right and left heart catheterization, coronary arteriography and left ventriculography is cardiac arrhythmia.

Pre-Procedure Lab

BUN	5 0	Creatinine	0.8		
Na	140	K+	4.3	Glucose	1-6
Hgb	14.0	Hct	40.9		
PTT	23.2	PT	11.4		

Technique

Primary vascular access was achieved through a 5 French arterial sheath inserted into the right femoral artery and an 8 French sheath into the right femoral vein. JL4, JR4, and pigtail diagnostic catheters were used. A 7 French thermodilution Swan-Ganz catheter was used for right heart pressures. A total of 105 cc of non-ionic contrast was administered

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[redacted]

Last Name: [redacted] **First Name:** [redacted]
Medical Record # [redacted]

Hemodynamics

Site	A	V	Systolic	Diastolic	Mean	EDP
LV			119			9
Aorta			115	77	96	
Right Atrium	6	4			2	
Right Ventricle			26			6
Pulmonary Artery			24	5	13	
Pulmonary Capillary Wedge	10	9			6	

Oximetry – Site Data

Site	Location	Total Hb	O2 Saturation	O2 Content
MPA		14	72	13.8
Ao		14	96.9	18.4

Cardiac Outputs

Method	Heart Rate	Cardiac Output (L/Min)	Cardiac Index (L/Min/m2)	AV O2 Difference
Thermodilution	63	6.77	3.09	4.6
Fick		6.85	3.13	

Lesion Findings

Right coronary artery: Normal.
Left main coronary artery: Normal.
Left anterior descending coronary artery: Normal. Diagonal branches are normal.
Left circumflex coronary artery: Normal. Marginal branches are normal.

Left Ventriculogram

Left ventriculogram was performed in the RAO projection. Estimated ejection fraction is 60% with normal LV wall motion analysis.

Complications

None

Final Diagnosis

Normal coronary arteries.

Recommendation

Electrophysiologic study.

[redacted] M.D.

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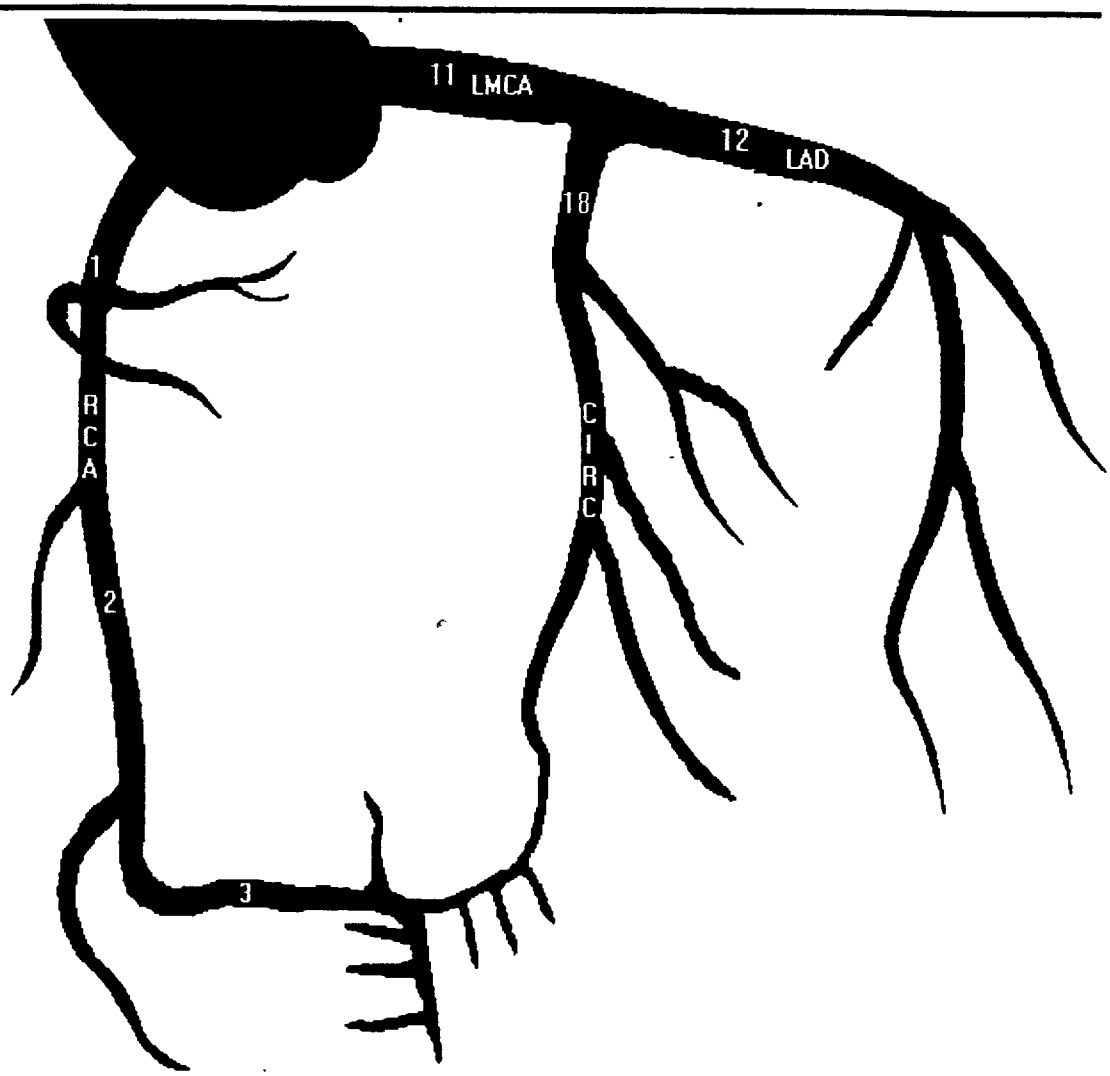
[redacted]

000014

Vessel Tree

Case ID Number: [redacted]
Patient ID:
Cathing Physician [redacted] MD

Patient Last Name: [redacted]
Patient First Name:



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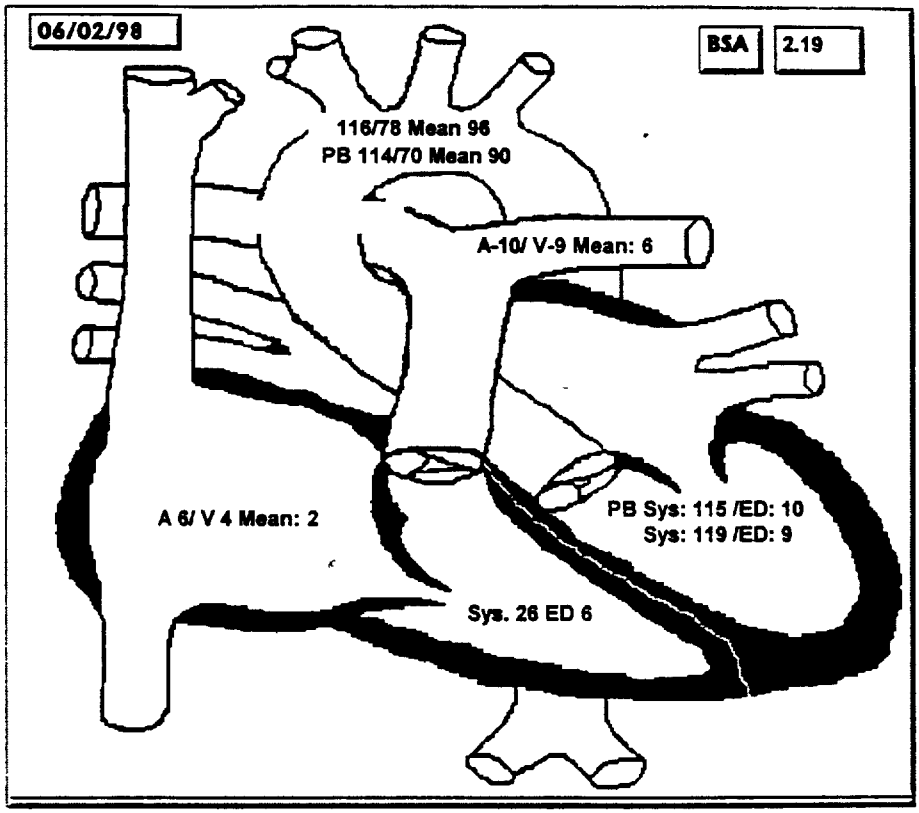
Hemodynamic Summary

[redacted]



[redacted]

PROGRESS RECORD

[redacted]

C R .
C R .

Date	Note progress in case, complications, consultations, change in diagnosis, condition on discharge, instructions to patient	Date

CARDIAC CATHETERIZATION LABORATORY REPORT PROGRESS NOTE

DATE: 06-02-98

CATHETERIZING PHYSICIAN: Dr [redacted]

ASSISTANT CATHETERIZING PHYSICIAN:

PROCEDURE PERFORMED:

FINDINGS:

END DIASTOLIC PRESSURE(APPROXIMATE):

EJECTION FRACTION (APPROXIMATE):

MEDICATIONS ADMINISTERED:

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POST PROCEDURE CONDITION: DISTAL PULSES:

CLEAN: CLEAN CONTAMINATED INFECT [redacted]

000017

[redacted]

PHYSICIAN SIGNATURE

[redacted]

[redacted] M.D.

Dictated: 06-05-98
Transcribed: 06-22-98

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[redacted]

ELECTROPHYSIOLOGY STUDY REPORT

Name: [redacted]

[redacted].: [redacted] Billing No.: DOB: [redacted] Age: 28
in. Wt: lbs. BSA: Sex: F
Study Date: 06/03/98 Patient Type:

Referring Physician: [redacted]

Physician Performing Study: [redacted], M.D.

Assistants: [redacted] M.D.

Study Number: [redacted]

Pre-medication: Valium 5 mg. p.o.

CLINICAL DIAGNOSIS:

The patient is a 28-year-old female with no prior cardiac history. The patient was resuscitated from an out-of-hospital cardiac arrest, where ventricular fibrillation was documented on 5/28/98 and brought to [redacted] Of note, the patient had taken an over-the-counter medication, Herbalife, to try to lose weight the day of the event. The patient had a myocardial infarction ruled out and was transferred to [redacted] where she had a normal cardiac catheterization, including normal coronaries, normal LV function, and normal right heart pressure. The patient was referred for an EP study.

Of note, review of the EKG's from [redacted] showed no evidence of QT abnormalities, no conduction abnormalities, and her electrolytes were normal.

INDICATION FOR STUDY: VF arrest

PROCEDURES:

Catheters Inserted	Entrance Sites	Number of Insertions
Tetrapolar 6 fr.	Rt Femoral vein	2

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[redacted]

[redacted]

ELECTRODES:
Esophageal Pill Electrodes: No

ECG Leads: I AVF V1

RECORDING SITES:

High right atrium
HIS Bundle location
R.V. outflow tract
Mid right atrium
R.V. apex

STIMULATION PROTOCOL:

Single atrial extrastimulus during atrial pacing
High right atrial pacing
Rapid atrial pacing
Single ventricular extrastimuli during v. pacing
Double ventricular extrastimuli
Triple ventricular extrastimuli
Twice diastolic threshold

STIMULATION SITES:

HRA
RVA
RVOT

MEDICATIONS GIVEN DURING PROCEDURE

MEDICATION	DOSE	UNITS	ROUTE	TIME GIVEN
None				

COMPLICATIONS: No

CATHETERS LEFT IN PLACE: No

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[redacted]

ELECTRODES:
Esophageal Pill Electrodes: No

ECG Leads: I AVF V1

RECORDING SITES:

High right atrium
HIS Bundle location
R.V. outflow tract
Mid right atrium
R.V. apex

STIMULATION PROTOCOL:

Single atrial extrastimulus during atrial pacing
High right atrial pacing
Rapid atrial pacing
Single ventricular extrastimuli during v. pacing
Double ventricular extrastimuli
Triple ventricular extrastimuli
Twice diastolic threshold

STIMULATION SITES:

HRA
RVA
RVOT

MEDICATIONS GIVEN DURING PROCEDURE

MEDICATION	DOSE	UNITS	ROUTE	TIME GIVEN
None				

COMPLICATIONS: No

CATHETERS LEFT IN PLACE: No

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REVIEW/OSNIFS-FS
CLINICAL RESEARCH
RECEIVED

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[redacted] [redacted] [redacted]

[redacted]

RESULTS:

1. Normal resting intervals:
   RR= 904 ms
   AH= 90 ms
   HV= 45 ms
2. Normal sinus node function with the maximum corrected sinus node recovery time= 236 ms at PCLP= 500 ms.
3. Normal AV node function with the AVNERP= 260 ms at PCL= 600 ms and Wenckebach cycle length= 280 ms.
4. Normal HIS Purkinje conduction with the HV interval= 45 ms and no prolongation with rapid atrial pacing.
5. RV apex stimulation:
   a) PCL= 600 ms VERP= 200 ms
      PCL= 400 ms VERP= 200 ms
   b) Programmed stimulation with up to three premature stimuli, cycle length 500/400 ms, did not induce any sustained ventricular arrhythmias. A maximum three complex non-sustained VT was induced.
6. RV outflow tract stimulation:
   a) PCL= 500 ms VERP= 220 ms
      PCL= 400 ms VERP= 230 ms
   b) Programmed stimulation with up to three premature stimuli, cycle length 500/400 ms, did not induce any sustained ventricular arrhythmias. A maximum three complex self-terminating VT was induced with programmed stimulation.
7. Burst pacing in the high right atrium was performed at 80 milliseconds to induce afib. The rate of afib was only 140-160 ms. There was no evidence of pre-excitation. The afib self-terminated in less than one minute.

RECOMMENDATIONS:

The patient had a normal EP study with no evidence of pre-excitation, no inducible ventricular arrhythmias, and no other abnormality found that could possibly explain the VF arrest. Will talk with Dr. [redacted] concerning the results of the test.

[redacted] M.D.

[redacted]:
Dictated: 06-03-98
Transcribed: 06-22-98

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[redacted]

[redacted]

RESULTS:

1. Normal resting intervals:
   RR= 904 ms
   AH= 90 ms
   HV= 45 ms
2. Normal sinus node function with the maximum corrected sinus node recovery time= 236 ms at PCLP= 500 ms.
3. Normal AV node function with the AVNERP= 260 ms at PCL= 600 ms and Wenckebach cycle length= 280 ms.
4. Normal HIS Purkinje conduction with the HV interval= 45 ms and no prolongation with rapid atrial pacing.
5. RV apex stimulation:
   a) PCL= 600 ms VERP= 200 ms
      PCL= 400 ms VERP= 200 ms
   b) Programmed stimulation with up to three premature stimuli, cycle length 500/400 ms, did not induce any sustained ventricular arrhythmias. A maximum three complex non-sustained VT was induced.
6. RV outflow tract stimulation:
   a) PCL= 500 ms VERP= 220 ms
      PCL= 400 ms VERP= 230 ms
   b) Programmed stimulation with up to three premature stimuli, cycle length 500/400 ms, did not induce any sustained ventricular arrhythmias. A maximum three complex self-terminating VT was induced with programmed stimulation.
7. Burst pacing in the high right atrium was performed at 80 milliseconds to induce afib. The rate of afib was only 140-160 ms. There was no evidence of pre-excitation. The afib self-terminated in less than one minute.

RECOMMENDATIONS:

The patient had a normal EP study with no evidence of pre-excitation, no inducible ventricular arrhythmias, and no other abnormality found that could possibly explain the VF arrest. Will talk with Dr. [redacted] concerning the results of the test.

[redacted]

[redacted] M.D.

Dictated: 06-03-98
Transcribed: 06-22-98

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[redacted]

[redacted]

ELECTROPHYSIOLOGY STUDY REPORT

Name: [redacted]

[redacted] Billing No.: [redacted] DOB: [redacted] Age:

Ht: in. Wt: lbs. BSA: Sex: F

Study Date: 06/04/98 Patient Type:

Referring Physician: [redacted]

Physician Performing Study: [redacted], M.D.

Assistants:

Study Number: [redacted]

Pre-medication: Valium 10 mg. orally

CLINICAL DIAGNOSIS:

Ms. [redacted] is a 27-year-old woman status post cardiac arrest with no evidence of structural heart disease or inducible ventricular arrhythmia. The patient was referred for insertion of a non-thoracotomy implantable defibrillator.

INDICATION FOR STUDY: Implantable defibrillator testing

PROCEDURES:

Catheters Inserted	Entrance Sites	Number of Insertions

ELECTRODES:

Esophageal Pill Electrodes: No

ECG Leads: I AVF V1

RECORDING SITES:

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[redacted]

[redacted]

STIMULATION PROTOCOL:

STIMULATION SITES:

MEDICATIONS GIVEN DURING PROCEDURE

MEDICATION	DOSE	UNITS	ROUTE	TIME GIVEN
Kefzol 1 g. IV				
Propofol				

COMPLICATIONS: No

CATHETERS LEFT IN PLACE: No

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[redacted]

RESULTS:

1. The patient was prepped and draped in a sterile fashion. 1% Lidocaine was infused over the left pectoral area. A left pectoral subcutaneous pocket was formed. Hemostasis was achieved. A CPI Model #0125 Serial #308261 pacing and defibrillating lead was inserted via the left subclavian vein using a modified Seldinger technique and positioned in the right ventricular apex under fluoroscopic guidance. The lead was secured to the pectoralis fascia using a suture tie and 2-0 silk. Final pacing thresholds were measured at 0.4 volts and 0.6 milliamps at a pulse width of 0.5 milliseconds. The measured lead impedance was 646 ohms with a measured R-wave of 24 millivolts. This was felt to be satisfactory and the lead was connected to a CPI Ventak Mini III Model #1782, Serial #[redacted] implantable defibrillator. Using the device, after the patient was adequately sedated, a 1 joule test shock was administered during sinus rhythm. The measured shocking in lead impedance was 50 ohms. Ventricular fibrillation was induced using rapid ventricular pacing. The device successfully detected and defibrillated the patient to a slow idioventricular rhythm which then converted to sinus rhythm with a single 17 joule shock. The measured shock in lead impedance was 48 ohms. After five minutes, this was repeated. The device again detected and defibrillated the patient to sinus rhythm with a single 17 joule shock. The measured shocking lead impedance was then changed to 48 ohms. The device was implanted. The wound was closed in three layers using 2-0 and 3-0 Vicryl. The wound was steri-stripped and dressed. The patient awoke uneventfully and left the EP Laboratory in satisfactory condition.
2. The device was left in the active mode with the rate cutoff of 185 bpm. The first shock energy was programmed to 17 joules. The remaining shock energies were set at 31 joules. VVI pacing was set at a lower rate of 40 bpm with an output of 4.0 volts at a pulse width of 0.5 milliseconds.

[redacted] M.D.

[redacted]: [redacted]
Dictated: 06-04-98
Transcribed: 06-22-98

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[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

ELECTROPHYSIOLOGY STUDY REPORT

Name: [redacted]

[redacted].: [redacted] Billing No.: DOB: [redacted] Age:
in. Wt: lbs. BSA: Sex: F

Study Date: 06/05/98 Patient Type:

Referring Physician: [redacted]

Physician Performing Study: [redacted], M.D.

Assistants:

Study Number: [redacted]

Pre-medication: None

CLINICAL DIAGNOSIS:

Ms. [redacted] is a 28-year-old woman who underwent insertion of a CPI Mini III, Model #1782 ICD yesterday. She now returns to the Electrophysiology Laboratory for pre-discharge testing.

INDICATION FOR STUDY: Implantable defibrillator testing

PROCEDURES:

Catheters Inserted	Entrance Sites	Number of Insertions

ELECTRODES:

Esophageal Pill Electrodes: No

ECG Leads: I AVF V1

RECORDING SITES:

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[redacted]

[redacted]

STIMULATION PROTOCOL:

STIMULATION SITES:

MEDICATIONS GIVEN DURING PROCEDURE

MEDICATION	DOSE	UNITS	ROUTE	TIME GIVEN
Versed				
Propofol				

COMPLICATIONS: No

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CATHETERS LEFT IN PLACE: No

RESULTS:

1. The patient's device was interrogated. No recent events were detected. The measured R-wave was 13.8 millivolts with a pacing threshold of less than 0.6 volts at a pulse width of 0.5 milliseconds. The measured lead impedance was 548 ohms. Ventricular fibrillation was induced after the patient was adequately sedated. The device successfully detected and defibrillated the patient to sinus rhythm with a single 17 joule shock. The measured shock in lead impedance was 44 ohms. The patient awoke uneventfully and left the [redacted] in satisfactory condition.
2. The device was left in the active mode with rate cutoff of 185 bpm. The first shock energy was programmed to 17 joules. The remaining shock energies were programmed to 30 joules. VVI pacing was set at a lower rate of 40 bpm with an output of 4.0 volts at a pulse width of 0.5 milliseconds.

RECOMMENDATIONS:

The patient underwent successful insertion of a non-thoracotomy implantable defibrillator. Wound instructions were given. She will be seen in the outpatient office in two weeks.

000028

[redacted]

[redacted] M.D.

Dictated: 06-05-98
Transcribed: 06-22-98

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000029

[redacted]

[redacted]

STIMULATION PROTOCOL:

STIMULATION SITES:

MEDICATIONS GIVEN DURING PROCEDURE

MEDICATION	DOSE	UNITS	ROUTE	TIME GIVEN
Versed				
Propofol				

COMPLICATIONS: No

CATHETERS LEFT IN PLACE: No

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RESULTS:

1. The patient's device was interrogated. No recent events were detected. The measured R-wave was 13.8 millivolts with a pacing threshold of less than 0.6 volts at a pulse width of 0.5 milliseconds. The measured lead impedance was 548 ohms. Ventricular fibrillation was induced after the patient was adequately sedated. The device successfully detected and defibrillated the patient to sinus rhythm with a single 17 joule shock. The measured shock in lead impedance was 44 ohms. The patient awoke uneventfully and left the [redacted] in satisfactory condition.
2. The device was left in the active mode with rate cutoff of 185 bpm. The first shock energy was programmed to 17 joules. The remaining shock energies were programmed to 30 joules. VVI pacing was set at a lower rate of 40 bpm with an output of 4.0 volts at a pulse width of 0.5 milliseconds.

RECOMMENDATIONS:

The patient underwent successful insertion of a non-thoracotomy implantable defibrillator. Wound instructions were given. She will be seen in the outpatient office in two weeks.

000030

[redacted]

Patient Loc:
Status: D
B #: [redacted]

DOB: [redacted] Sex: F [redacted]

[redacted]

Radiology Consultation

Confidential Medical Information. If you received this document in error, please call [redacted] immediately.

Physician: [redacted]
[redacted] 5-Jun-98 9:53 AM Requested by: [redacted]
CHEST PA&LAT VIEWS
Billing Codes: [redacted]

Diagnosis:
ANGINA

PA and lateral views of the chest show a normal size heart. An internal defibrillator is present. The lung fields are clear. The hilar structures and mediastinum are normal. The bony structures are intact.

IMPRESSION:
Internal defibrillator. No acute disease.

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Approved by:
[redacted] /signed by/ [redacted] M.D.

Transcribed on: 6-Jun-98 10:01 AM by [redacted]
Finalized on: 6-Jun-98 1:24 PM by [redacted] M.D.

C O P Y

[redacted]

06/05/1998 06:22:37 AM [redacted]
Born [redacted] Female

[redacted]
Dept: [redacted]
Room: [redacted]
Oper: [redacted]

000032

Rate	75
PR	150
QRSD	80
QT	382
QTc	427

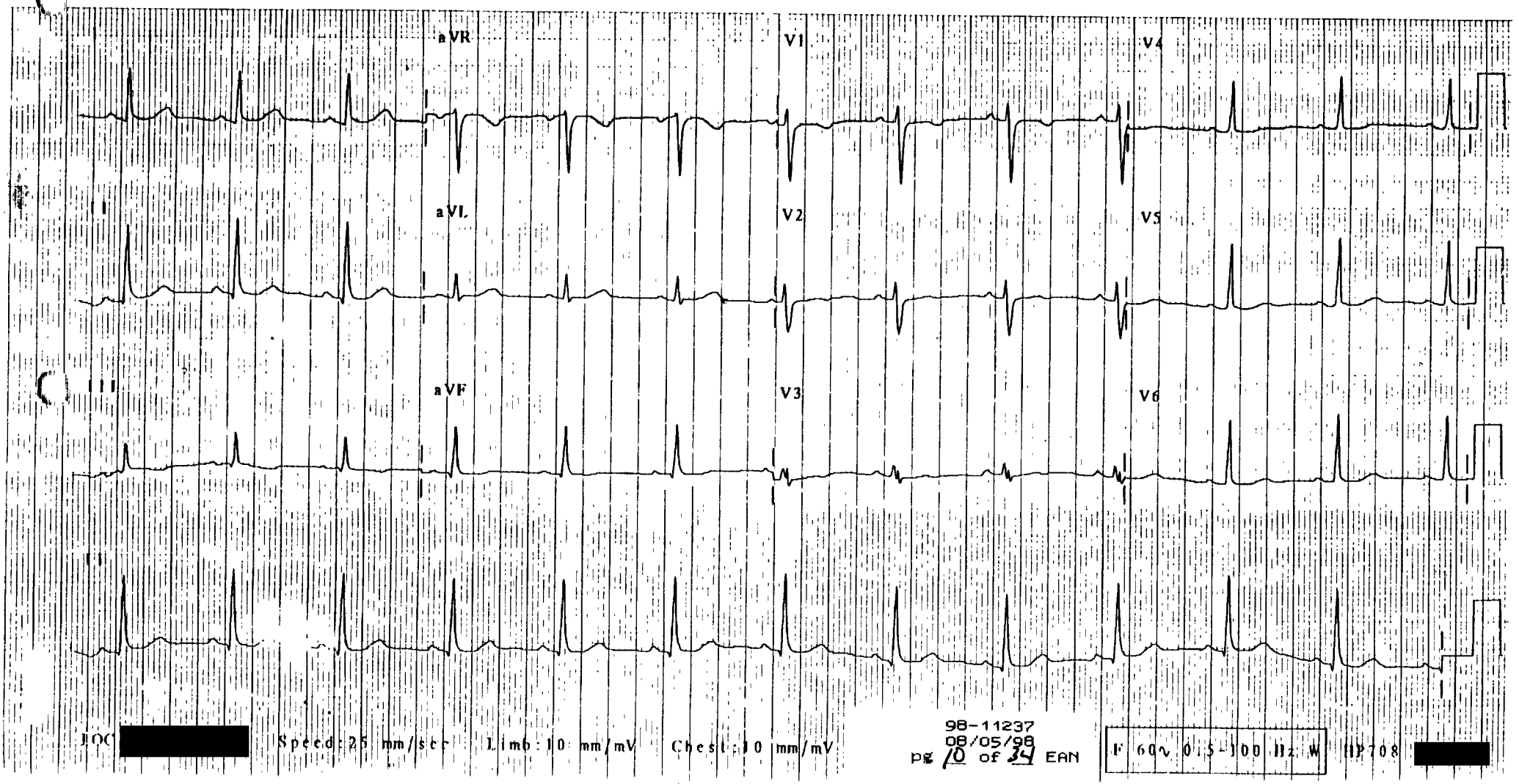
--AXIS--

P	26
QRS	44
T	10

. Normal sinus rhythm, rate 75.....Normal P axis, PR, rate & rhythm
. Nonspecific Anterolateral T abnormalities.....T neg, T/QRS ratio <.07 I,L,V2-V6

- BORDERLINE ECG -

PRELIMINARY-MD MUST REVIEW



[redacted] 5 JUN 1998 6:22:37AM [redacted]

29 yrs Female

PR 150
QRSD 80
QT 382
QTc 427

--AXES--
P 26
QRS 44
T 10

(NSR). Normal sinus rhythm, rate 75 - - - - - - Normal P axis, PR, rate & rhythm
(TOAL). Nonspecific Anterolateral T abnormalities - - T neg, T/QRS ratio <.07 I,L,V2-V6
- BORDERLINE ECG -

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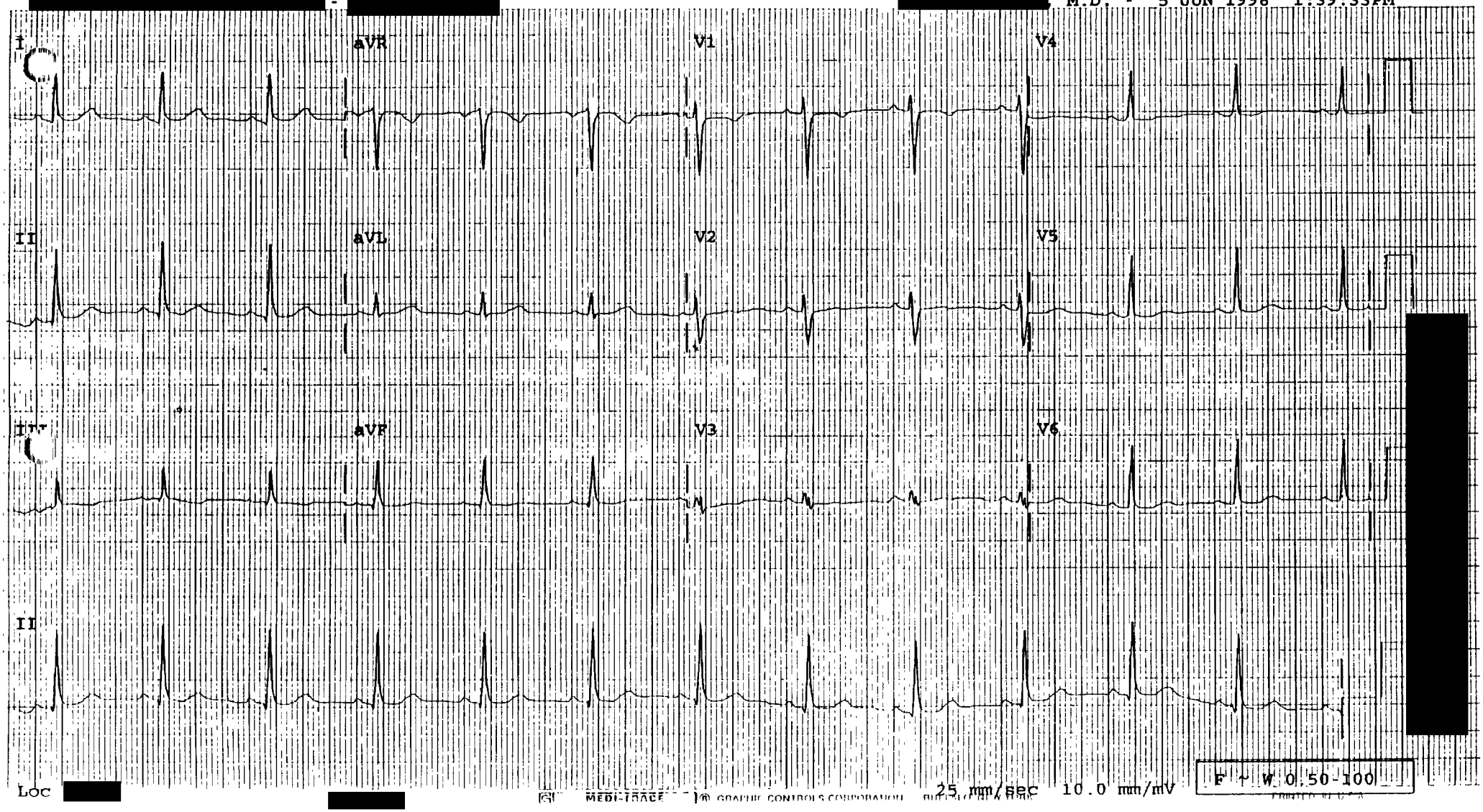
Tech Room [redacted]

[redacted] M.D. - 5 JUN 1998 1:39:33PM



[redacted]

06/01/1998 12:41:38 PM [redacted]
28 years Female

[redacted]

BP:

[redacted]

Room: [redacted]
Oper: [redacted]

Rx:
Dx:

Rate	65
PR	142
QRSD	79
QT	372
QTc	387

--AXIS--

P	-1
QRS	27
T	5

. Normal sinus rhythm, rate 65.....Normal P axis, PR, rate & rhythm

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Requested by: [redacted]

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- NORMAL ECG -

PRELIMINARY-MD MUST REVIEW